FEB 1 0 2004

K033800

CAPIOX® Cardiotomy Reservoir

Submitter Information:
This premarket notification is submitted by:

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Terumo Cardiovascular Systems
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Date of Preparation: November 3, 2003

Device Names:

Proprietary Name:	CAPIOX® Cardiotomy Reservoir
Common Name:	Blood Reservoir
Classification:	CPB Reservoirs are classified as Class II devices.

Predicate Device:
The CAPIOX® Cardiotomy Reservoir is substantially equivalent in intended use, materials, design, technology and principles of operation, and performance to the following devices:

- CAPIOX® RX05 Hardshell Reservoir (Cardiotomy Section) - K022115.
- Medtronic Minimax Hardshell Reservoir (Cardiotomy Section) - K933586.

Intended Use:
The CAPIOX® Cardiotomy Reservoir is designed to facilitate the removal of particulate matter and micro air bubbles from blood that is aspirated from the thoracic cavity and/or the left ventricle, and store it during extra corporeal circulation. The device may be used for procedures lasting up to 6 hours.

Principles of Operation/Technology:
The CAPIOX® Cardiotomy Reservoir is used as a blood storage device during and after cardiopulmonary bypass procedures. The patient's blood enters the reservoir from the thoracic cavity and/or the left ventricle. Typically, the blood is pulled into the reservoir via suction.

The blood that is drawn from the patient enters the device via the blood inlet ports and suction ports that are positioned above the cardiotomy filter that is contained within the reservoir. The blood passes through a defoamer (to facilitate the removal of air from the blood) and through a filter for mechanical entrapment/removal of particulate matter from the blood.

Blood exits the device via gravity through the blood outlet port and is subsequently pumped through the remainder of the cardiopulmonary bypass circuit.

Design and Materials:
The *design* of the CAPIOX® Cardiotomy Reservoir is comprised of a hardshell casing that serves as a blood containment system within the bypass circuit. The upper portion of the reservoir consists of a hardshell lid assembly that contains the necessary inlet ports and vent ports. The total capacity of the reservoir is 1000 mL.

The cardiotomy section of the CAPIOX® Cardiotomy Reservoir contains a defoamer and a filter to facilitate air removal and the removal of particulates from suctioned blood entering the reservoir.

The generic *materials* used in the CAPIOX® Cardiotomy Reservoir are polycarbonate, polypropylene, PET, polyurethane, silicone rubber, PMMA-PHEMA and Terumo's X-Coating polymer solution.

Performance Evaluations:
The performance of the CAPIOX® Cardiotomy Reservoir is substantially equivalent to the performance of the cardiotomy sections of the aforementioned predicate devices. The following tests were conducted to demonstrate equivalence in performance:

- Filter Defoaming – Cardiotomy Section
- Pressure Drop – Cardiotomy Section
- Filtration Efficiency – Cardiotomy Section
- Effects Upon Cellular Blood Components
- Pressure Integrity Testing
- Tubing Connection Strength
- Filter Breakthrough Time

Substantial Equivalence Comparison:
The CAPIOX® Cardiotomy Reservoir is substantially equivalent to cardiotomy section of the predicate devices as indicated below:

Intended Use: The CAPIOX® Cardiotomy Reservoir and the predicate CAPIOX® RX05 Hardshell Reservoir share the same intended uses. The cardiotomy section of each device is used to facilitate the removal of particulate matter and micro air bubbles from blood that is aspirated from the thoracic cavity and/or the left ventricle, and store it during extra corporeal circulation. Each device may be used for procedures lasting up to 6 hours. The respective cardiotomy sections of these two devices are identical. Their intended uses are identical.

Principles of Operation/Technology: The CAPIOX® Cardiotomy Reservoir and the predicate CAPIOX® RX05 Hardshell Reservoir utilize the exact same technology in their respective operations. With each device, the patient's blood enters the reservoir from the thoracic cavity and/or the left ventricle. Typically, the blood is pulled into the reservoir via suction.

The blood that is drawn from the patient enters the devices via the blood inlet ports and suction ports that are positioned above the cardiotomy filter that is contained within the reservoirs. The blood passes through a defoamer (to remove air from the blood) and through a filter (for mechanical entrapment/removal) of particulate matter from the blood.

Blood exits the devices via gravity through the blood outlet port and is subsequently pumped through the remainder of the cardiopulmonary bypass circuit.

The principals of operation and employed technology of the two devices are identical.

Design and Materials: The design of the CAPIOX® Cardiotomy Reservoir is identical to the predicate CAPIOX® RX05 Hardshell Reservoir except that it does not contain a venous filter. As such, the materials are also identical for the two devices, excepting that a venous filter is not present in the CAPIOX® Cardiotomy Reservoir. There are no new and/or additional materials utilized in the CAPIOX® Cardiotomy Reservoir that are not also utilized in the predicate CAPIOX® RX05 Hardshell Reservoir.

Performance: The cardiotomy section of the CAPIOX® Cardiotomy Reservoir is exactly the same as the cardiotomy section of the predicate CAPIOX® RX05 Hardshell Reservoir. As such, there are no performance differences between the cardiotomy sections of the two devices. The removal of the venous filter does not alter the performance of the cardiotomy filter, as the two filters operate and perform independently of each other. Additionally, comparative studies between the CAPIOX® Cardiotomy Reservoir and the predicate Medtronic Minimax Reservoir further demonstrate the *substantial equivalence* of the proposed device to another legally marketed device.

Substantial Equivalence Summary:
In summary, the CAPIOX® Cardiotomy Reservoir and the predicate CAPIOX® RX05 Hardshell Reservoir are substantially equivalent in intended use, principles of operation/technology, design and materials, and performance. Any noted differences between the devices do not raise new issues of safety and effectiveness. Additionally, equivalence is also demonstrated between the CAPIOX® Cardiotomy Reservoir and the Medtronic device (with respect to select performance evaluations).

Additional Safety Information:
- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Biocompatibility studies were conducted on the CAPIOX® RX25 Hardshell Reservoir – which is constructed of the same materials as the CAPIOX® Cardiotomy Reservoir. As such, Terumo makes reference to the RX25 biocompatibilty studies to support the requirements for this submission.

  The biocompatibility studies were conducted on the CAPIOX® RX25 Hardshell Reservoir as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to satisfy all biocompatibility test specifications.

Conclusion:

In summary, the CAPIOX® Cardiotomy Reservoir is substantially equivalent in intended use, principles of operation/technology, design and materials, and performance to the cardiotomy section of the predicate CAPIOX® RX05 Hardshell Reservoir (K022115) and to the Medtronic Minimax Reservoir (Cardiotomy Section) - K933586.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2004

Terumo Cardiovascular Systems Corporation
c/o Garry A. Courtney MBA, RAC
Sr. Regulatory Affairs Specialist
125 Blue Ball Road
Elkton, MD 21921

Re: K033800
CAPIOX® Cardiotomy Reservoir
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiotomy Reservoir
Regulatory Class: Class II (two)
Product Code: DTN
Dated: December 3, 2003
Received: December 5, 2003

Dear Mr. Courtney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Richmond

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033800

Device Name: **CAPIOX® Cardiotomy Reservoir**

Indications For Use:

The CAPIOX® Cardiotomy Reservoir is designed to facilitate the removal of particulate matter and micro air bubbles from blood that is aspirated from the thoracic cavity and/or the left ventricle, and store it during extra corporeal circulation. The device may be used for procedures lasting up to 6 hours.

Garry A. Courtney, MBA, RAC
Terumo Cardiovascular Systems

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Donna R. Vochmes
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K033800